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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/822,043 01/17/90 SDRACHE

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SUITE 500
3000 K STREET, N.W.
WASHINGTON, DC 20007-5005

1872/1116

EXAMINER

ART UNIT

PAPER NUMBER

19

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

11/16/93

☒ This application has been examined ☒ Responsive to communication filed on 9/7/93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-4, 22 are pending in the application.
Of the above, claims 1-2 and 7-15 are withdrawn from consideration.
2. ☒ Claims 3-6 and 16-17 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 18-22 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Part III DETAILED ACTION

1. The amendment filed by applicant on 9/7/93 has been made of record.

Claims 1-22 are pending.

Claims 1-2 and 7-15 are drawn to non-elected inventions.

Claims 3-6 and 16-17 are cancelled and replaced by claims 18-22.

Response to Amendment

2. Applicant's arguments filed 9/7/93 have been fully considered but they are deemed to be persuasive in-part.

3. The rejection under 35 USC 112, first paragraph, on page 3 lines 9-15 of the Office action mailed 3/4/93 is withdrawn in view of applicant's arguments.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, ie. as failing to provide an enabling

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disclosure. The reasons for this rejection are of record in paper no. 13, mailed 3/4/93.

Applicant argues, on page 7 of the amendment filed on 9/7/93, that "without supportive evidence that treatment of cancer is highly unpredictable, the examiner says nothing at all about diagnosis in the present context". The claimed invention has the utility to diagnose cancer. However, the specification remains objected to in relation to "the treatment of cancer." The art of treating cancer is highly unpredictable because even though many researchers have been working for years to treat cancer, there is no known single effective treatment of cancer. A combination of many treatments is generally used to combat cancer. Moreover, due to the variety of cancers, it is inconceivable that one type of polypeptide could treat all types of cancer. Thus, the only way to demonstrate that the compounds of the present are effective in the treatment of all types of cancer is to show extensive clinical data using the modes of administration encompassed by the specification.

Thus, applicant's have not enabled the use of the present invention as a therapeutic agent.

5. The objection to the specificaliton under 35 USC 112, first paragraph, relating to lack of written description pertaining to "X" is maintained. Applciant argues that "X" is "likely" to be asparagine, threonine or serine. Applicant is not sure what is

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in this position. Additionally, "potentially" glycosylated residues means that the residues could not be glycosylated and, if it is not, then the residue at that position can be any of the 20 naturally occurring amino acids.

Claim 22 (as amended) is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

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6. The specification is also objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, ie. as failing to provide an enabling disclosure. The reasons for this rejection are of record in paper no. 13, mailed 3/4/93.

Applicant's, at examiners suggestion, have eliminated "comprises" and replaced it with "contains". (Only claim 22 contains this terminology). "Comprises" and "contains" are synonymous in that they both are considered to be OPEN language, ie. not only is the applicant claiming the specific fragment stated in the claims, but also amino acids on either side of said sequence. Since this is the case, the applicant has not enabled the method of making fragments which "contain" the given sequences since the rest of the compound which possesses a given sequence is unduly broad because of the indefinite nature of such terminology used to describe the disclosed and claimed compounds. "Contain" suggests additional elements not specifically taught or

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suggested by applicant's disclosure. Since claim 22 is directed to a fragment, it is unclear if applicant intends to limit the fragment to the specific sequences.

This rejection is maintained.

Claim 22 (as amended) is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

7. The rejection under 35 USC 101 that the claimed invention lack patentable utility is withdrawn in view of applicant's amendment. The claimed invention does have practical utility in that it can diagnose cancer.

8. The rejection under 35 USC 101 that the claimed invention is directed to nonstatutory subject matter is withdrawn in view of applicant amendment.

9. Claim 22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The reasons for this rejection are of record in paper no. 13, mailed 3/4/93.

All rejections under 35 USC 112, second paragraph has been withdrawn in view of applicant's amendment except the rejection pertaining to "comprises". Even though applicant, at Examiner's suggestion replaced "comprises" with "contains", they are both synonymous. This issue was addressed earlier in this action.

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The use of "having" is suggested by the Examiner. The Examiner regrets any confusion created in the previous Office action.

10. The rejection under 35 USC 102 (b) as being anticipated by Liotta is withdrawn in view of applicant's amendment.

11. The rejection under 35 USC 103 as being unpatentable over Liotta in view of Yarmush is withdrawn in view of applicant's amendment.

New Grounds of Rejection

12. Claims 18-22 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 states "said protein and said fragment raises antibody". It is unclear how a fragment or protein can "raise" an antibody? An antibody can be raised against a protein but a protein cannot raise an antibody.

13. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION

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IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


MERRELL C. CASHION, JR.
SUPERVISORY PATENT EXAMINER
GROUP 180

Sheela J. Huff
November 15, 1993